## UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

LIFELINK PHARMACEUTICALS, INC,	) CASE NO. 5:07-cv-00785-JG
Plaintiff,	) ) JUDGE JAMES S GWIN
V	DEFENDANTS' WAIORA USA, INC.; WAIORA INTERNATIONAL, LLC;
NDA CONSULTING, INC., et al.	WAIORA INTERNATIONAL, LLC; WAIORA HOLDINGS, LLC; WAIORA, LLC; WAIORA AUSTRALIA, LLC;
Defendants	WAIORA HONG KONG, LLC AND STANLEY J. CHERELSTEIN'S FIRST AMENDED ANSWER TO FIRST AMENDED COMPLAINT AND
	COUNTERCLAIM  (JURY DEMAND ENDORSED  HEREON)

Defendants Waiora USA, Inc; Waiora International, LLC; Waiora Holdings, LLC; Waiora, LLC; Waiora Australia, LLC; Waiora Hong Kong, LLC; and Stanley J. Cherelstein ("Defendants") respond to Plaintiff's First Amended Complaint as follows:

- Deny for want of knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraphs 1, 2 and 3
- Admit that Waiora USA, Inc ("Waiora USA") is a Florida corporation with its principal place of business at 791 Park of Commerce Boulevard, Suite 300, Boca Raton, Florida, and that it sells supplemental dietary and nutritional products through various sources, including distributors and the Internet, and deny all other allegations set forth in Paragraph 4.

- 3. Admit that Defendant Waiora International, LLC is a Florida limited liability company with its principal place of business in Boca Raton, Florida and deny all other allegations set forth in Paragraph 5.
- 4. Admit that Defendants Waiora Holdings, LLC, Waiora, LLC, Waiora Australia, LLC and Waiora Hong Kong, LLC are Florida limited liability companies having their principal place of business in Boca Raton, Florida, that the website www waiora.com may have stated that products are available in the United States, Canada, Hong Kong, Taiwan and Japan and deny all other allegations set forth in Paragraph 6.
- Admit that Stanley Cherelstein is the President and CEO of Waiora USA, that he has known Deitsch, that he did work at Unicity, Inc. with Deitsch, that he was employed as the controller of Phar Mor, that he and Deitsch serve as members of the Board of Directors of Nutra Pharma Corp. and deny all other allegations set forth in Paragraph 7.
- Admit that Kelley Spears resides in Hudson, has purchased products from Waiora
  USA and deny all other allegations set forth in Paragraph 8
- 7. Admit that Adrian Goad is a customer of Waiora USA and deny all remaining allegations set forth in Paragraph 9 for want of knowledge and information sufficient to form a belief as to their truth.
- Admit that Rowan Emrys is a customer of Waiora USA and deny all remaining allegations set forth in Paragraph 10 for want of knowledge and information sufficient to form a belief as to their truth.
- 9. Deny, for want of knowledge and information to form a belief as to their truth, the allegations set forth in Paragraph 11.
  - Deny the allegations set forth in Paragraphs 12, 13, 14 and 15.

- Admit that Purify Your Body, LLC is a customer of Waiora USA and deny all remaining allegations set forth in Paragraph 16 for want of knowledge and information sufficient to form a belief as to their truth.
- Deny the allegations set forth in Paragraph 17 for want of knowledge and information sufficient to form a belief as to their truth.
  - Deny the allegations set forth in Paragraph 18.
- Deny the allegations set forth in Paragraph 19 for want of knowledge and information sufficient to form a belief as to their truth.
  - Deny the allegations set forth in Paragraphs 20, 21, 22, 23, 24 and 25
- Deny the allegations set forth in Paragraphs 26 and 27 for want of knowledge and information sufficient to form a belief as to their truth
- With respect to Paragraphs 28, 29 and 30, the terms of any agreement speak for themselves and otherwise deny the allegations set forth therein
- 18. Deny the allegations set forth in Paragraph 31 for want of knowledge and information sufficient to form a belief as to their truth.
  - Deny the allegations set forth in Paragraphs 32
- Deny the allegations set forth in Paragraphs 33, 34, 35, 36, 38, 39, 40, 41, 42, and 43 for want of knowledge and information sufficient to form a belief as to their truth.
- Admit that a website advertised Natural Cellular Defense and at some point stated that the product was protected by a patent, that literature referenced the patent and deny all other allegations set forth in Paragraph 37.
- Admit that an email was sent, that it reads for itself, and deny all remaining allegations set forth in Paragraph 44.

- Deny the allegations set forth in Paragraph 45
- With respect to Paragraph 46, restate and incorporate by reference their responses to Paragraphs 1 through 45.
  - Deny the allegations set forth in Paragraphs 47, 48, 49, 50 and 51.
- With respect to Paragraph 52, restate and incorporate by reference their responses to Paragraphs 1 through 51
- Deny the allegations set forth in Paragraphs 53, 54 and 55 for want of knowledge and information sufficient to form a belief as to their truth
- With respect to Paragraph 56, restate and incorporate by reference their responses to Paragraphs 1 through 55.
  - 29 Deny the allegations set forth in Paragraphs 57, 58, 59, 60, 61, 62, 63 and 64.
- With respect to Paragraph 65, restate and incorporate by reference their responses to Paragraphs 1 through 64.
  - Deny the allegations set forth in Paragraphs 66, 67, 68 and 69
- With respect to Paragraph 70, restate and incorporate by reference their responses to Paragraphs 1 through 69.
  - Deny the allegations set forth in Paragraph 71.
- With respect to Paragraph 72, restate and incorporate by reference their responses to Paragraphs 1 through 71.
  - 35. Deny the allegations set forth in Paragraphs 73 and 74.
  - 36 Deny all allegations not specifically admitted herein

# SECOND DEFENSE

37. Plaintiff fails to state a claim upon which relief can be granted.

### THIRD DEFENSE

38 Some or all of Plaintiff's claims are barred by the doctrines of estoppel, laches, and/or waiver

### **FOURTH DEFENSE**

39 Some or all of Plaintiff's claims are barred due to Plaintiff's unclean hands.

### FIFTH DEFENSE

40. Plaintiff's fraud and conspiracy claims fail to state the allegations with particularity.

### **SIXTH DEFENSE**

Some or all of Plaintiff's claims are barred by the statute of limitations

## SEVENTH DEFENSE

Some or all of Plaintiff's claims are barred by the intervening acts of other parties.

### **EIGHTH DEFENSE**

Plaintiffs have failed to mitigate damages.

### **NINTH DEFENSE**

The claims of the patent in suit are invalid and/or unenforceable.

### TENTH DEFENSE

45 Many of the Defendants named by Plaintiff have not sold any products.

### ELEVENTH DEFENSE

Some or all of Plaintiff's claims are barred because Defendants are not the real parties in interest

### TWELFTH DEFENSE

47. Some or all of Plaintiff's claims are barred as the manufacturer, not customers, is the primary party in interest.

### THIRTEENTH DEFENSE

Plaintiff's fraud and conspiracy claims must fail due to the lack of reasonable reliance

### **FOURTEENTH DEFENSE**

49. Plaintiff's fraud and conspiracy claims must fail due to the truthfulness of the alleged misrepresentation

### FIFTEENTH DEFENSE

50. The claims of the patent in suit are invalid and unenforceable for not complying with the requirements of 35 U.S.C. § 101, et seq

### SIXTEENTH DEFENSE

Plaintiff's fraud and conspiracy claims fail to state the allegations with particularity

### SEVENTEENTH DEFENSE

52. Plaintiff's fraud and conspiracy claims are barred by the economic loss rule.

### **EIGHTEENTH DEFENSE**

The claims of the patent in suit are invalid and unenforceable for failure to comply with the applicable rules, regulations and directives of the U.S. Patent & Trademark Office pertaining to patents.

### **NINETEENTH DEFENSE**

54. Defendants do not infringe, and have not infringed, directly or indirectly, any valid and enforceable claim of the '045 Patent literally or under the Doctrine of Equivalents

#### TWENTIETH DEFENSE

55. Plaintiff's claim of patent infringement is barred by license and/or contract.

### TWENTY-FIRST DEFENSE

Plaintiff's claim of patent infringement is barred by patent invalidity arising from an on sale bar

#### TWENTY-SECOND DEFENSE

Plaintiff's claim of patent infringement is barred by the invalidity of the patent claims as being obvious over prior art references and/or anticipated by prior art references.

#### TWENTY-THIRD DEFENSE

Any defense raised by any other Defendant relating to the validity of the patent in suit

### TWENTY-FOURTH DEFENSE

59. Defendants reserve the right to raise additional defenses as discovery in this case proceeds and/or may warrant.

WHEREFORE, having fully answered, Defendants request that the First Amended Complaint be dismissed with prejudice, costs to Plaintiff.

### **COUNTERCLAIM**

Waiora USA, Inc; Waiora International, LLC; Waiora Holdings, LLC; Waiora, LLC; Waiora Australia, LLC; Waiora Hong Kong, LLC; and Stanley J. Cherelstein (hereinafter referred to collectively as "Counterclaim-Plaintiffs"), by and through their undersigned counsel,

hereby sue Plaintiff/Counterclaim-Defendant, Lifelink Pharmaceuticals, Inc. ("Lifelink" or "Counterclaim-Defendant"), and state as follows:

- 1. On June 9, 2000, Harvey Kaufman filed a U.S. Patent Application entitled "Epithelial Cell Cancer Drug."
- 2. This application was granted and U.S. Patent No. 6,288,045 (the "045 Patent") was issued on September 11, 2001 listing Lifelink as the assignee of the patent.
  - 3. Lifelink purports to be the current owner of the '045 Patent.
- On April 24, 2007, Lifelink filed its First Amended Complaint claiming that the '045 Patent is valid and enforceable and that Defendants infringed on the '045 Patent. Lifelink seeks damages for this alleged infringement.
- 5. The claims of Plaintiff's '045 Patent are invalid and/or unenforceable for not complying with the requirements of Title 35 U.S.C. including but not limited to Sections 101, 102, 103, 112, et seq
- The patent in suit is invalid and/or unenforceable for failure to comply with the applicable rules, regulations and directives of the United States Patent & Trademark Office pertaining to patents.
- 7... Pursuant to 28 U.S.C. § 2201(a) the '045 Patent should be declared invalid and/or unenforceable.
- Due to the suit filed by Counterclaim-Defendant Lifelink, there exists between these Counterclaim-Plaintiffs and Counterclaim-Defendants an actual controversy regarding the validity and effect of the '045 Patent exists
- 9 A judicial declaration of invalidity is necessary and appropriate in order to resolve this controversy.

WHEREFORE, Counterclaim-Plaintiffs seek a declaratory judgment that some or all claims of the '045 Patent are invalid and/or unenforceable and any other relief that this Court deems just and proper

WHEREFORE, Counterclaim-Plaintiffs ask this Court to enter judgment as follows:

- A That the patent in suit be declared invalid;
- B. That the patent in suit be declared to be unenforceable;
- C. That the patent in suit be declared non-infringed;
- D. That Counterclaim Plaintiffs be awarded their costs, expenses and reasonable attorney fees, under 35 U S C. §285 and other applicable statutes and laws; and
- E. That Counterclaim Plaintiffs be granted such other and further relief as this Court may deem just and proper.

Respectfully submitted,

### /s/David L. Drechsler

David L Drechsler #0042620 Ryan J Morley #0077452 BUCKINGHAM, DOOLITTLE & BURROUGHS, LLP 1375 E 9<sup>th</sup> Street, Suite 1700 Cleveland, Ohio 44114 Telephone: (216) 621-5300

Facsimile: (216) 621-5440
Email: ddrechsler@bdblaw.com
rmorley@bdblaw.com

Philip R. Wiese #0067058 Louis F. Wagner #0010768 3800 Embassy Parkway, Suite 300 Akron, Ohio 44333-8332

Telephone: (3)

(330) 376-5300 (330) 258-6559

Email:

Facsimile:

pwiese@bdblaw.com

Case: 5:07-cv-00785-JG Doc #: 96 Filed: 08/15/07 10 of 11. PageID #: 655

# JURY DEMAND

Answering Defendants and Counterclaim Plaintiffs hereby demand a trial by the maximum number of jurors allowed by law on all issues so triable.

/s/David L. Drechsler

Case: 5:07-cv-00785-JG Doc #: 96 Filed: 08/15/07 11 of 11. PageID #: 656

### **CERTIFICATE OF SERVICE**

I hereby certify that on August 15, 2007, a copy of the foregoing *Defendants' Waiora USA*, *Inc.*; *Waiora International*, *LLC*; *Waiora Holdings*, *LLC*; *Waiora*, *LLC*; *Waiora Australia*, *LLC*; *Waiora Hong Kong*, *LLC and Stanley J. Cherelstein's First Amended Answer to First Amended Complaint and Counterclaim* was filed electronically in accordance with the Court's Electronic Filing Guidelines Notice of this filing will be sent to all parties by operation of the court's electronic filing system. Parties may access this filing through the court's system.

/s/David L. Drechsler	

«CL 2:318298\_v1»